



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,500	08/20/2003	Ross C. Terrell	INH1001USC3	6567

7590 01/27/2004

John C. McNeirney
Vice Presiden & Chief Technical Officer
MINRAD, Inc.
847 Main Street
Buffalo, NY 14203

EXAMINER

SHIPPEN, MICHAEL L

ART UNIT	PAPER NUMBER
----------	--------------

1621

DATE MAILED: 01/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/644,500

Applicant(s)

TERRELL, ROSS C.

Examiner

MICHAEL L. SHIPPEN

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 18-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 18-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION***Claim Rejections - 35 USC § 103¹***

Claims 1-13 and 18-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muffler (DE 2823969) in view of Regan (USP 3683092). Muffler teaches the instant process except for the specific reactants claimed. It is noted that Muffler makes reference to hydrofluorides of nitrogen bases which differs from the claims reciting a mixture containing hydrogen fluoride and an amine. However, the reference indicates that the hydrofluorides can be generated *in situ* from the hydrogen fluoride and the amine, note the top of page 9 of the translation provided by applicants in the parent application. Muffler does not teach some of the instant starting materials (and the corresponding final products). Such reactants differ only as to substituents that are removed from the reaction site and do not enter into the reaction. One would not expect the different substituents to affect the outcome of the reaction. One would be motivated to use the instant reactants in the prior art process since one would readily recognize the reactants necessary to afford the final products having the desired structure. Nothing patentable is seen in the use of a new starting material in an otherwise old process. Moreover, Regan clearly teaches that the instant reactants are known to react with fluorination agents to afford the same products. It would be readily

¹The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1621

apparent to one that the instant starting material could be used in the Muffler process to afford the instant products. Moreover, it is considered that the prior art provides further motivation to modify the prior art. Particularly note pages 4 and 5 of the translation provided in the parent application, where the advantages over other process are pointed out. One would be motivated to use the Muffler process in order to realize the advantages suggested in the reference. Some of the claims recite the method of preparing the starting material. This is a standard method of preparation as shown by Regan, note Example 2. With respect to multi-step synthetic procedures involving a combination of individually well known chemical reactions, it has been held that one of ordinary skill in the relevant art is charged with knowledge of the individual chemical reactions and their combination to produce a desired end product would have been obvious, *In re Payne*, 203 USPQ 245; *In re Winslow*, 151 USPQ 48; *In re Kamlet*, 88 USPQ 106.

The examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). It is noted that, except for the claims that require the preparation of the $(\text{CF}_3)_2\text{CHOCH}_2\text{Cl}$, the claimed process differs from the Muffler process only as to the reactant (and corresponding product) used. Muffler standing alone would render the use of the reactant obvious since the claimed reactant

is quite similar to the reactants used in the prior art. As for combining the references, as pointed out above, Muffler teaches a number of advantages in the process over other known fluorination process. One would be motivated to use the Muffler process in order to realize the advantages suggested in the reference.

Electronic and steric factors of the fluorinated methyl groups would not have been expected to affect the outcome of the reaction. First, the reaction takes place at the chloro group which is removed from the fluorinated methyl groups of the $(\text{CF}_3)_2\text{CHOCH}_2\text{Cl}$ reactant. One would not expect the electronic and steric factors of the fluorinated methyl groups so removed to greatly influence the outcome of the reaction. Second, Muffler teaches the use of reactants, such as, $(\text{CF}_3)\text{CICH}_2\text{OCH}_2\text{Cl}$ and 2-fluoro-2-chlorocyclopropyl chloromethyl ether, which also possess electronic and steric factors, afford the products one would expect.

Assertions that it is unpredictable whether the process would have worked based on the statement in Regan that antimony fluorides did not give the desired product is not found persuasive of patentability. The fact that a different reagent behaved in an unexpected manner does not show that one would expect the Muffler fluorination agents not to be suitable. In fact applicants obtain the product one would predict from the teaching of Muffler.

Double Patenting²

Claims 1-13 and 18-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of USP 5969193. Although the conflicting claims are not identical, they are not patentably distinct from each other because the conflicting claims are clearly within the purview of the instant broader generic claims. The conflicting claims of the patent differ from the instant claims by reciting the presence of water. The instant claims are open to the presence of water and such is clearly intended to be within the purview of the instantly claimed invention as set forth in the specification.

Conclusion

This is a continuation of applicant's earlier Application No. 10/193,786. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL**

² The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Michael L. Shippen** whose telephone number is **(703) 308-4635**. The Examiner's normal tour of duty is 7:30 AM to 4:00 PM. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is **(703) 308-1235**. The official group FAX machine number is **703-872-9306**.

MShippen
January 21, 2004



MICHAEL L. SHIPPEN
PRIMARY EXAMINER
ART UNIT 1621